Claim 42. (twice amended):

42. An article comprising a [porous] polymeric tube having a circumference wherein the circumference of said [porous] polymeric tube increases in response to the application of a circumferentially distending force, wherein the [porous] polymeric tube itself limits [exhibits] recoil [of] to 14 percent or less following removal of the circumferentially distending force.

REMARKS

I. PRELIMINARY REMARKS

Claims 1-117 are pending in the application. Of these, claims 36-41 and 98-117 are withdrawn from consideration as a result of the previous restriction requirement; these claims are now canceled. Claims 1-35 and 42-97 stand rejected.

Independent claims 1, 33 and 42 are amended herein in response to the outstanding rejections.

II. APPLICANTS' INVENTION

The present invention relates to a polymeric tube which circumferentially distends from an initial circumference upon the application of a circumferentially distending force such as applied by an internal pressure, and which exhibits minimal recoil following the removal of the circumferentially distending force. The polymeric tube preferably has a second circumference larger than the initial circumference (the second circumference achieved by circumferential distension by force) which remains substantially unchanged by further increasing force. The polymeric tube itself provides the circumferential distensibility up to the limit, without need of additional plastically deformable components such as metal stents. It is useful as a liner for pipes and vessels, particularly those having irregular luminal surfaces to which the polymeric tube can smoothly conform. The tube is most preferably made from porous PTFE, in which form it is particularly useful as a liner for both living and prosthetic blood vessels. The limiting second circumference is of particular value for applications of this type in that it can be used to prevent further undesirable dilitation of the blood vessel to which it is fitted.

III. REJECTION OF CLAIMS 1-5, 24-30, 33-35, 42-49, 51-55, 57-61, 63-67 and 69-97 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY LEE, US 5,123,917.

Lee describes an expandable intraluminal graft in the form of an expandable polymeric tubular graft in combination with a metallic stent. The Examiner points out that the expansion limit of the graft layer is reached due to the expansion of the stent which will permit only a

predetermined expansion due to the stent configuration and structure. The claims as amended specify that the polymeric tube itself provides the ability to limit the circumference. Neither Lee nor any of the other cited art provides such a tube or makes any suggestion of how to provide such a tube.

IV. REJECTION OF CLAIMS 1, 2, 5, 24-30, 33-35, 42-48, 51-54, 58-60, 63-66, 69, 70, 72, 74, 76, 78, 80, 82, 84 AND 86-97 UNDER 35 USC 102(b) AS BEING ANTICIPATED BY RHODES, US 5,122,154.

Rhodes describes a stent and tube combination which is very similar to that of Lee. It also requires a stent to provide a limit to circumferential distension. For the same reasons described above in Paragraph IV with regard to Lee, the amended claims are not anticipated by Rhodes.

V. REJECTION OF CLAIMS 6-16, 18, 19 and 21-23 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF EILENTROPP, US 4,791,966.

Lee is described above. Eilentropp teaches a tube of non-porous PTFE formed by a helically-wrapped layer of non-porous PTFE tape. The tape has a trapezoidal cross section, thicker at the center of the tape than at the edges which allows for the tape edges to overlap during wrapping and still result in a tube of relatively uniform wall thickness. The Examiner states that it would have been obvious to have formed the outer layer of Lee with the helically wrapped tape per Eilentropp because the helically layered tube would have been merely an alternate and analogous method of forming another layer on the Lee device.

The present invention differs from Lee as noted above in that it does not require a stent to limit the circumferential distension. As noted above, Lee neither teaches or suggests the present invention according to the amended claims. The addition of Eilentropp renders the present claims even less obvious.

The background of the present specification at page 2, lines 29-31 briefly describes GORE-TEX® Vascular Grafts which are ePTFE tubes having an exterior layer of ePTFE helically-applied tape. These commercially available vascular grafts (several million implanted to date) represent the physical embodiment of the combination of Lee and Eilentropp except that they do not include the stent components of Lee. The purpose of the helical wrapping on these grafts is specifically to prevent circumferential dilitation of the tube. Eilentropp makes absolutely no suggestion that a helically wrapped tube might provide any circumfrential distensibility. There is no suggestion in the combination of Lee and Eilentropp as to how a distensible, helically-wrapped graft might be achieved. Further, there is no suggestion to combine these references.

Simply adding the wrap of Eilentropp to the graft component of Lee would result in a dilitation-resistant graft analogous to the commercial GORE-TEX Vascular Graft; indeed, the graft of Lee would be rendered non-distensible (and therefore non-functional) by adding the helical

wrap of Eilentropp. The specification at Figure 4, page 11, lines 10-16 and page 11, line 33 to page 13, line 8 describes how the inventive porous polymeric tube of the present invention is made and how it differs from the commercial GORE-TEX Vascular Graft. There are significant steps included in the process flow chart of Figure 4 that result in the tube of the present invention, steps that are not required to make a non-distensible helically reinforced tube such as would result from the simple combination of Lee and Eilentropp. The prior use of helical wrapping such as represented by the GORE-TEX Vascular Graft and Eilentropp clearly teaches away from distensibility. The present distensible graft incorporating a helical wrap is non-obvious over the combination of Lee and Eilentropp.

VI. REJECTION OF CLAIMS 17 AND 18 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF EILENTROPP ('966) AS APPLIED TO CLAIM 14 ABOVE, AND FURTHER IN VIEW OF SUMMERS, US 5,607,445.

Lee and Eilentropp are described above; Eilentropp simply adds the use of a helical wrap to construct a tubular form. As noted by the Examiner, Summers teaches that a stent may be either straight (with two ends) or branched (with three ends). He further concludes that it would have been obvious to have formed the modified Lee stent/graft in a branched form, and that the branched form might also include tapers.

Applicants acknowledge the prior existence of both tapered and branched grafts. The cited combination of references including Summers does not, however, teach or suggest in any way how the porous polymeric tube of the present invention might be provided with in a circumferentially distensible form resistant to recoil or with a limiting second circumference, regardless of whether embodied in straight, branched or tapered form. Thus, for the reasons already described above, these claims (as amended) are not obvious over the cited references.

VII. REJECTION OF CLAIMS 31 AND 32 UNDER 35 USC 103(a) AS BEING UNPATENTABLE OVER LEE ('917) IN VIEW OF SUMMERS ('445).

This rejection is analogous to the previous rejection described in Paragraph VII above, except that it does not include the helical wrap of Eilentropp. The presence or lack of the helical wrap does not affect the reasons for patentability of these claims; the amended claims are not obvious over this combination for the same reasons described in Paragraph VI above.

VIII. REJECTION OF CLAIMS 20, 50, 56, 62 AND 68 UNDER 35 USC 103(A) AS BEING UNPATENTABLE OVER LEE ('917) ALONE OR LEE IN VIEW OF EILENTROPP ('966).

The references are described above. The claims in question pertain to the securing of the tube to blood vessels by the use of sutures. Applicants acknowledge the substantial prior use of sutures for securing grafts to blood vessels; however, in the claimed combination there is no suggestion to suture grafts of the type described by claim 1 (amended). Consequently these dependent claims are also non-obvious and patentable.

CONCLUSION

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,

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